

Applicant : Miller  
Appl. No. : 10/595605  
Examiner : Roland Dinga  
Docket No. : 13634.4013

#### Remarks

Claim 55 has been indicated to be allowable. Claim 55 has been rewritten in independent form as new claim 63.

Claims 1—17, 44—49, and 56—62 have been cancelled without prejudice and claims 18, 21—34 and 36—41 have been amended to depend from elected independent base claim 42.

Claims 58—62 were objected to for informalities and rejected under 35 USC 112 as indefinite. Objections to and rejections of claims 58—62 under 35 USC 112 are moot in view of applicant's cancellation of these claims.

Claims 1—6 were rejected under 35 USC 102(b) as anticipated by Kantrowitz, which rejection is moot in view of applicant's cancellation of these claims.

Claims 1 and 8—10 were rejected under 35 USC 102(e) as anticipated by Peters '784, which rejection is moot in view of applicant's cancellation of these claims.

Claims 11—14 were rejected under 35 USC 102(e) as anticipated by Peters '784, which rejection is moot in view of applicant's cancellation of these claims.

Claims 44—49 were rejected under 35 USC 102(e) as anticipated by Peters '783, which rejection is moot in view of applicant's cancellation of these claims.

Claims 56—57 were rejected under 35 USC 102(e) as anticipated by Peters '597, which rejection is moot in view of applicant's cancellation of these claims.

Claims 56—57 were rejected under 35 USC 102(e) as anticipated by Peters '597, which rejection is moot in view of applicant's cancellation of these claims.

Claims 7 was rejected under 35 USC 103 as unpatentable over Kantrowitz in view of Hegde, which rejection is moot in view of applicant's cancellation of this claim.

Claims 42—43 were rejected under 35 USC 102(e) as anticipated by Peters '783 and claims 42 and 50—54 were rejected under 35 USC 102(e) as anticipated by Peters '784. Both Peters are directed to an intravascular heart assist device comprising an inelastic, i.e., plastic, shell with a flexible membrane sealingly attached to the periphery of the shell. Peters 2004/0097784 reads in pertinent part:

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[0027] Referring firstly to FIGS. 1 and 2 there is shown a first embodiment of an intravascular heart assist device 10 according to the invention. The device 10 includes an inelastic, preferably plastic, shell 12 and a membrane 14, sealingly attached to periphery of the shell 12. The membrane 14 defines an inflatable space 16 between it and the interior of the shell 12.

Similarly, Peters 2004/0097783 reads in pertinent part:

[0063] FIG. 1 is a schematic side view of an ascending aorta 10 and a heart assist device 16 in accordance with an embodiment of the invention. The device 16 has a relatively inelastic, preferably plastic, shell 17 and a flexible membrane 18 sealingly attached to the periphery of the shell 17.

[0074] FIG. 9 is a schematic side view of a heart assist device 16 in accordance with another embodiment of the invention. The device 16 has a relatively inelastic, preferably plastic, shell 17 and a flexible membrane 18 sealingly attached to the periphery of the shell 17. The membrane 18 defines an inflatable space 19 between it and the interior of the shell 17.

[0088] In FIG. 18 the heart assist device is a patch device 16 attachable to the ends of the aorta 10, at stitches 22, formed by removing a length of the aorta. The patch device 10 is in the general shape of a truncated toroid with an externally facing hump that forms the inflatable space 19. The membrane 18 is attached to the patch device 16 about the periphery of the hump. The hump is disposed external to a line on the radially outer side, or passing through, the diameter of the mid point cross section of the aorta 10.

[0089] The flexible membrane 18 substantially replicates the shape of the interior of the hump when the fluid is withdrawn from the space 19. The membrane 18, when the fluid is introduced into the space 19, is expanded close to, but not abutting, the adjacent interior wall of the aorta, as is shown in phantom line.

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The balloon designs of Peters, which do not have a radius of curvature between the shell and flexible member where they are glued together, have been found to result in stress concentrations at the sealing joint between the shell and flexible membrane about the periphery of the shell, which has been found to lead to the rapid failure of the balloons.

In contrast to the balloon designs described in Peters, the claimed invention is directed to a flexible one-piece balloon having a neck portion and a balloon body, wherein the balloon body is one-piece including a first annular portion, a second circular or oval portion and a flexure portion in which the annular portion is connected to the neck and in which the flexure portion maintains a radius of curvature even when the second balloon portion is drawn against the first annular portion upon deflation of the balloon. By having a totally flexible balloon, compliance with the body of the patient is ensured and the possibility of abrasion or wear on bodily tissues from the device is avoided. Furthermore, the maintenance of a radius of curvature in the flexure zone avoids stress concentration which can lead to balloon failure.

Thus, both Peters do not anticipate the claims 42—43, 18, 21—34, 36—41, and 50—55 as both Peters do not teach, describe or suggest each of the limitations of these claims. Specifically, both Peters do not teach, describe or suggest

an integrally formed balloon body, the body including:

a substantially annular first body portion connected at its inner periphery to the second end of the neck portion; and

a substantially oval or circular second body portion and

an annular inwardly concavely curved flexure portion formed integrally with the outer peripheries of the first and second body portions, wherein the flexure portion is adapted to maintain a radius of curvature on its inner surface during deflation of the balloon when an inside surface of the second body portion is drawn into contact with at least a portion of

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an inside surface of the first body portion, and a convex shape during inflation of the balloon

as claimed in claim 42. According, claims 42—43, 18, 21—34, 36—41, and 50—55 meet the requirements for patentability under 35 USC 102.

Prompt and favorable action on the merits of the claims is earnestly solicited. Should the Examiner have any questions or comments, the undersigned can be reached at (949) 567-6700.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 15-0665.

Respectfully submitted,  
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By:   
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